

### **Amendments to the Specification:**

Please replace paragraph [0001] with the following amended paragraph:

Priority is claimed to provisional patent application serial no. 60/319,346, filed June 25, 2002 ~~and to provisional patent application serial no. 60/319,370, filed June 28, 2002.~~

Please replace paragraph [0002] with the following amended paragraph:

The present invention ~~related~~ relates, in general, to edible films and, more particularly, to pullulan-free edible film compositions containing Magnolia Bark ~~extract~~ Extract and to methods of making the film compositions.

Please replace paragraph [00010] with the following amended paragraph:

In another embodiment of the present invention, the oral product is a ~~pullulan-free~~ pullulan-free edible film composition that includes an effective amount of a film forming agent, and an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises Magnolia Bark Extract ~~extract~~.

Please replace paragraph [00011] with the following amended paragraph:

In yet another embodiment of the invention, a method of oral cleansing includes applying a pullulan-free edible film to the oral cavity, where the edible film includes an effective amount of a film forming agent, and an effective amount of an antimicrobial agent where the antimicrobial agent comprises Magnolia Bark Extract ~~extract~~.

Please replace paragraph [00012] with the following amended paragraph:

In still another embodiment of the invention, a method of making a pullulan-free edible film includes forming an aqueous solution that includes a maltodextrin, a hydrocolloid, and a filler, adding an effective amount of an antimicrobial agent to the aqueous solution, where the antimicrobial agent comprises Magnolia Bark Extract ~~extract~~, and drying the aqueous solution to form a dry edible film.

Please replace paragraph [00013] with the following amended paragraph:

A further embodiment of the invention includes a treatment method for reducing the number or activity of bacteria in the oral cavity by providing an edible film composition

including Magnolia Bark Extract ~~extract~~ in an amount sufficient to kill or deactivate oral bacteria, and causing a person in need of the treatment to consume the edible film composition, whereby the bacteria in the oral cavity of the person is reduced or inactivated by the treatment.

Please replace paragraph [00017] with the following amended paragraph:

In vitro tests were conducted with three subgingival plaque bacteria associated with oral malodor. The MIC (Minimum Inhibitory Concentrations) study protocol is as follows. Chlorhexidine was used as a positive control and sterile water was used as a negative control. Menthol and Tween 80 was used as a solvent for Magnolia Bark Extract. ~~Nine-six-well~~ Nine six-well microtiter plates were used for this study. Each well contained  $5 \times 10^5$  colony forming units/ml of bacteria, serially diluted agents and bacterial growth medium. All bacterial cultures were incubated at 37°C and stationary. Bacterial growth was estimated spectrophotometrically at 660 nm, after 48 hours. The MIC for each test bacteria was defined as the minimum concentration of test compound limiting turbidity to < less than 0.05 absorbance at 660 nm.

Please replace paragraph [00018] with the following amended paragraph:

The MBC (Minimum bactericidal concentrations) were determined using the ~~96~~ nine six-well microtiter plate serial dilutions as described above for MIC studies. Serial dilution of cultures in wells showing no visible growth were performed and 10 microliters of culture were plated in triplicate on blood agar plates. Viable colonies were scored after incubation of the plates for 48 hours at 37°C. For each test bacterium, the number of CFU/ml were determined in the initial inoculum. The MBC was defined as the lowest concentration of a test compound that killed at least 99.9% of the cells present in the initial inoculum.

Please replace paragraph [00022] with the following amended paragraph:

In an embodiment, the invention comprises a treatment method for reducing the number or activity of bacteria in the oral cavity comprising the steps of providing an oral composition comprising Magnolia Bark Extract ~~extract~~ in an amount sufficient to kill or deactivate oral bacteria and causing a person in need of the treatment to consume the oral

composition whereby the bacteria in the oral cavity of the person is reduced or inactivated by the treatment.

Please replace paragraph [00028] with the following amended paragraph:

In an embodiment, the oral composition is formulated to deliver at least 0.005% concentration of Magnolia Bark extract to the oral cavity.

Please replace paragraph [00029] with the following amended paragraph:

In an embodiment, the oral composition is formulated to deliver at least 0.01 % concentration of Magnolia Bark Extract ~~extract~~ to the oral cavity.

Please replace paragraph [00030] with the following amended paragraph:

In an embodiment, the oral compositions is formulated to deliver at least 0.1% concentration of Magnolia Bark Extract ~~extract~~ to the oral cavity.

Please replace paragraph [00031] with the following amended paragraph:

Given that Magnolia Bark extract is a hydrophobic compound, there are several methods, which may be used to enhance the release of the Magnolia Bark Extract ~~extract~~ from the oral composition. In a chewing gum product, the gum base is hydrophilic which would facilitate the release of the Magnolia Bark Extract ~~extract~~. In an oral composition, the Magnolia Bark Extract ~~extract~~ may be encapsulated, spray dried, formulated into ~~the a~~ a coating, and combinations thereof.

Please replace paragraph [00032] with the following amended paragraph:

In general, a chewing gum composition typically comprises a ~~waterbulk~~ water-soluble bulk portion, a ~~waterchewable grams~~ water-insoluble chewable gum base portion and typically ~~waterflavoring~~ water-soluble flavoring agents. The ~~water~~portion dissipates with a portion of the flavoring agent over a period of time during chewing. The gum base portion is retained in the mouth throughout the chew.

Please replace paragraph [00037] with the following amended paragraph:

Preferred ranges for polyisobutylene are 50,000 to 80,000 GPC weight average molecular weight; ~~and for styrene~~ are styrene are 1:1 to 1:3 bound styrene; for polyvinyl

acetate are 10,000 to 65,000 GBC weight average molecular weight, with the higher molecular weight polyvinyl acetates typically used in bubble gum base, and for vinyl acetate laurate acetate laurate, a vinyl laurate content of 10.

Please replace paragraph [00038] with the following amended paragraph:

Natural elastomers may include natural rubber, such as smoked or liquid latex and guayule, as well as natural gums, such as jelutong, lechi caspi, perillo, sorva, massaranduba balata, massaranduba chocolate, nispero, rosindinha, chicle, gutta hang kang, and combinations thereof. The preferred synthetic elastomer and natural elastomer concentrations vary depending on whether the chewing gum in which the base is used is adhesive or conventional, bubble gum or regular gum, as discussed below. Preferred natural elastomers include jelutong, chicle, sorva and massaranduba balata.

Please replace paragraph [00043] with the following amended paragraph:

The base may or may not include wax. An example of a ~~wax~~ wax-free gum base is disclosed in U.S. Patent No. 5,286,500, the disclosure of which is incorporated herein by reference.

Please replace paragraph [00049] with the following amended paragraph:

If a low calorie gum is desired, a low caloric bulking agent can be used. Examples of low caloric bulking agents include: polydextrose; ~~Raftilose~~ raftilose, ~~Raftilin~~ raftilin; ~~Fructooligosaccharides~~ fructooligosaccharides (NutraFlora); Palatinose oligosaccharide; ~~Guar Gum Hydrolysate~~ guar gum hydrolysate (Sun Fiber); or indigestible dextrin (Fibersol). However, other low calorie bulking agents can be used.

Please replace paragraph [00050] with the following amended paragraph:

A variety of flavoring agents can also be used, if desired. The flavor can be used in amounts of about 0.1 to about 15 weight percent of the gum, and preferably, about 0.2% to about 5% by weight. Flavoring agents may include essential oils, synthetic flavors or mixtures thereof including, but not limited to, oils derived from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, other mint oils, clove oil, oil of wintergreen, anise and the like. Artificial flavoring agents and components may also be

used. Natural and artificial flavoring agents may be combined in any sensorially acceptable fashion. Flavoring may include a cooling agent to enhance the flavor and perceived breath freshening of the product. Cooling agents include menthol, ethyl p-menthane carboxamide, N,2,3-trimethyl-2-isopropyl-butanamide, menthyl glutarate ~~FEMA 4006~~ (Flavor Extract Manufacturing Association (FEMA 4006)), menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, N-tertbutyl-p-menthane-3-carboxamide, p-menthane-3-carboxylic acid glycerol ester, methyl-2-isopropyl-bicyclo (2.2.1), heptane-2-carboxamide, menthol methyl ether and combinations thereof.

Please replace paragraph [00051] with the following amended paragraph:

In addition, to the Magnolia Bark Extract ~~active ingredients~~ of the present invention, additional active ingredients or medicaments may be added for various purposes. If the medicament or active is water soluble in the chewing gum, it preferably will include a base/emulsifier system which leads to the desired concentration of the medicament in the saliva (more hydrophilic balance). If the medicament or active is water insoluble, the chewing gum preferably includes a base/emulsifier system which leads to the desired concentration of the medicament in the saliva (more lipophilic balance).

Please replace paragraph [00053] with the following amended paragraph:

Optionally, the chewing gum of the present invention may include additional breath freshening, anti microbial or oral health ingredients, such as ~~Food~~ food acceptable metallic salts selected from zinc and copper salts of gluconic acid, zinc and copper salts of lactic acid, zinc and copper salts of acetic acid, zinc and copper salts of citric acid and combinations thereof.

Please replace paragraph [00054] with the following amended paragraph:

Anti-microbial essential oils and flavor components such as peppermint, methyl salicylate, thymol, eucalyptol, cinnamic aldehyde, polyphosphate, pyrophosphate and combinations thereof may be added to the gum composition.

Please replace paragraph [00055] with the following amended paragraph:

Dental health ingredients such as fluoride salts, phosphate salts, proteolytic enzymes, lipids, anti-microbials, calcium, electrolytes, protein additives, dental abrasives and combinations thereof may also be added to the gum composition.

Please replace paragraph [00061] with the following amended paragraph:

In an embodiment of the present invention, an effective amount for anti microbial benefit of Magnolia Bark Extract is present in an edible film formulation. In an embodiment of the present invention, the amount of Magnolia Bark Extract is present in an amount up to 10% by weight of the edible film formulation. In an embodiment of the present invention, the amount of Magnolia Bark Extract is about 8% of the weight of the edible film product. In another embodiment, the Magnolia Bark Extract ~~extract~~ is present in the amount of about 5% by weight of the edible film product. Considering the potency of Magnolia Bark Extract ~~extract~~ as described in the in vitro studies above, about 1% by weight of the edible film product may also be effective in bactericidal properties.

Please replace paragraph [00073] with the following amended paragraph:

The medicaments can be delivered or released into the oral cavity for effective oral treatment, such as oral cleansing and/or breath freshening. In this regard, the film forming agent of the edible film can act to entrap the medicaments within the oral cavity thereby providing extended efficacy thereof. In doing so, it is believed that the ~~pullulan-free~~ pullulan-free edible film compositions of the present invention more uniformly release the medicament into the oral cavity for absorption via open wounds or mucous membrane in a greater manner than could be previously achieved. Moreover, it is also believed that the mixture of film forming agents of the present invention can entrap the medicament within the oral cavity for an extended period of time to prolong and enhance the effects of the medicament. In addition, by extending the contact time of the medicament within the oral cavity, the medicament is absorbed to a greater extent thereby increasing its bioavailability.

Please replace paragraph [00083] with the following amended paragraph:

In yet another embodiment of the present invention, and effective amount for anti-microbial benefit of Magnolia Bark Extract is present in a confectionery formulation. In an embodiment of the present invention, the amount of Magnolia Bark Extract is present in an amount up to 3% by weight of the confectionery product. In an embodiment of the present invention, the amount of Magnolia Bark Extract is 1% of the weight of the confectionery product. In another embodiment, the Magnolia Bark Extract ~~extract~~ is present in the amount of 0.01% by weight of the confectionery product. Considering the potency of Magnolia Bark Extract ~~extract~~ as described in the in vitro studies above, 0.005% by weight of the confectionery product s also effective in bactericidal properties.

Please replace the abstract with the following amended abstract:

#### ABSTRACT OF THE DISCLOSURE

A pullulan-free edible film composition for oral cleansing, breath freshening, and anti-microbial benefits includes a film forming agent and Magnolia Bark ~~extract~~ Extract. In a treatment process, an effective amounts amount of Magnolia Bark ~~extract~~ Extract is delivered to the oral cavity by the edible film for convenient oral cleansing and breath freshening benefits. A method of making the pullulan-free edible film composition includes forming an aqueous solution of film forming agents and Magnolia Bark ~~extract~~ Extract and drying the aqueous solution to form a dry edible film.